

REMARKS

In the prior Office Action, Examiner had allowed independent claim 44 over Lang (2003/0015208) and Faulkner (6,740,041), both of which were considered, and relied upon, in the prior Office Action. Instead of issuing a Notice of Allowance, as anticipated, Examiner has now issued another Office Action which rejects independent claim 44, and claims dependent therefrom, based on the same references: Lang and Faulkner.

Specifically, Examiner states:

Lang teaches a method to diagnose treat and prevent bone loss. In Lang a bone characteristic level such as bone mineral density is measured and therapy is prescribed based on the bone mineral density...Repeat measurements of the bone characteristic is taken over a period of time, which can be seconds, minutes, hours, days, months, or any interval there between...Lang does not explicitly disclose using a T-score as a measure of the bone mineral density, however it is well known in the art as disclosed by Faulkner that a raw bone mineral density value has limited meaning to a physician...so it is obvious to provide an established reference such as T-score to make the raw bone mineral density value of Lang useful. If the measurements of Lang results in a normal T-score, then a therapy such as a postponement of development of bone loss symptom can be prescribed such as taking a calcium supplement.

Examiner does not discuss, or allege, that the combination of Lang and Faulkner disclose any of the limitations relating to a gait analysis or gait characterization, which are part of independent claim 44:

- if the T-score is abnormal, conducting a **gait analysis** to yield a **gait characterization**;
- if the **gait characterization** is abnormal, measuring a bone marker concentration in at least one body fluid of said patient to yield a bone marker level having a value;
- prescribing a therapy based on at least one of the said **gait characterization**, said

- T-score, and bone marker level; and
- designating a future time to repeat said measurement of a bone characteristic level, said **gait analysis**, and said measurement of a bone marker concentration.

To establish a case of *prima facie* obviousness of a claimed invention, three basic criteria must be met. First, there must be some suggestion or motivation to combine the references, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Second, there must be a reasonable expectation of success. As stated in MPEP 2143.01, the fact that references can be hypothetically combined or modified is not sufficient to establish a *prima facie* case of obviousness. See *In re Mills*, 916 F.2d 680 (Fed.Cir. 1990). Finally, the prior art references must teach or suggest all the claim limitations. *In re Royka*, 490 F.2d 981 (CCPA 1974); MPEP 2143.03. Specifically, “all words in a claim must be considered when judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382 (CCPA 1970). Furthermore, in accordance with the Supreme Court’s decision in *KSR Int’l Co. v. Teleflex, Inc.* (US 2007) and new guidelines for examining obviousness under 35 U.S.C. Section 103, it is “now necessary to identify the reason” why a person of ordinary skill in the art would have combined the prior art elements, or at least describe the pertinence of the prior art elements set forth in the cited disclosure, in the manner presently claimed. Moreover, even if combined, the *Graham* factors require that a determination of the differences between combined prior art and the claims at issue is needed. Accordingly, based on the above, Examiner has simply not established a *prima facie* case of obviousness as a matter of law.

Furthermore, Applicant has reviewed both Lang and Faulkner and could not identify any teaching of conducting a gait analysis based upon an abnormal T-score or measuring a bone marker concentration if a gait characterization is abnormal, which are limitations in all pending claims. Accordingly, Applicant respectfully requests allowance of the pending claims.

Respectfully submitted,



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